UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/018,026 | 06/11/2002 | Atle Bjornerud | NIDN-10403 | 4684 |

36335 7590 09/14/2004

AMERSHAM HEALTH
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

| EXAMINER | |
|---|---|
| QADERI, RUNA S | |
| **ART UNIT** | **PAPER NUMBER** |
| 3737 | |

DATE MAILED: 09/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/018,026 | BJORNERUD ET AL. | |
| | Examiner | Art Unit | |
| | Runa S. Qaderi | 3737 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *29 October 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/29/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Specification*

The specification is objected to because it lacks a brief and detailed description of the drawings in the application. Correction is required. See MPEP § 601 and 18.23.

**Content of Specification**

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject

matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation.

There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(k) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

Examiner notes that claim 13 has been cancelled via First Preliminary Amendment filed 10/29/01. Examiner also noted that in both marked up and clean copy of claims, claim 13 is not listed. According to 37 CFR 1.121 when there is any amendment to a claim, a claim listing of all claims ever presented in the case must be supplied in ascending numerical order. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fahlvik (US 5,855,868) in view of Lewis et al. (US 5,055,288).

Fahlvik discloses a method of contrast enhanced MR angiography of the human or non-human animal body comprising administering into the vascular thereof a contrast effective amount of a contrast agent and thereafter imaging to assist in visualization of the vasculature (i.e. so called blood pool or angiographic contrast agents) by enhancing contrast between blood vessels and surrounding tissue or organ.

With respect to claims 3-5 and 15-17, Fahlvik discloses various compositions of the blood pool contrast agents of which include a superparamagnetic iron oxide, magnetic iron oxide particles coated with polysaccharides and an opsonization agent, and superparamagnetic iron oxide coated with starch, entire document.

The reference discloses the step of injecting or infusing the contrast agent into the vascular by conventional means, thereby satisfying the limitation of claims 6 and 18. The recitation to "injecting" is interpreted as a bolus administration by the Examiner.

With respect to claims 7-11 and 19-23 (more specifically to claims 8, 10, 20, and 22) Fahlvik generates both a $T_1$ and $T_2$ weighted images, column 8 lines 27-49, and (more specifically to claims 11 and 23) administers a first and a second contrast particles and thereafter imaging the region after each administration, column 7 lines19-32. Further with respect to claims 7-11 and 19-23 Fahlvik (more specifically claims 7, 9, 10, 19, 21, and 22) recites generation of pre-contrast images and temporally spaced post-contrast images that are time dependant on the uptake of the contrast particles.

The reference does not specifically recite the generation of the images during the first pass of the contrast agent and after the concentration of the contrast agent throughout the blood of the body has become substantially uniform. It would have been obvious to one of ordinary skill in the art at the time the invention was made to generate the images as claimed by applicant because the step of generating post contrast images temporally spaced dependant on the time of the uptake of the contrast particles both encompass and does not preclude from the applicant's limitations. The method of generating an MR contrast image to differentiate between the vascular and surrounding tissue or organ as taught by applicant is satisfied by the step of generating post contrast images temporally spaced dependant on the time of the uptake of the contrast particles.

Furthermore with respect to all the rejected claims although the reference discloses an MR imaging method of contrast enhanced MR angiography of the human or non-human animal body by enhancing contrast between blood vessels and surrounding tissue or organ, it does not specifically recite said organ as the kidney and accessing the physiological and morphological state of the kidney, accordingly.

The Lewis et al. reference discloses a vascular magnetic imaging method comprising administering a superparamagnetic metal oxide to the organ to allow one to image organ, tissue perfusion as well as blood flow, column 1 lines 21-23. The reference discloses said organ to include the brain, kidney, lung, and the heart. Furthermore the methods provide valuable information regarding the condition of the vessels, organs, or tissues including the presence of microocclusions, embolisms,

aneurysm, restricted blood flow, and the onset or recession of the arterial disease, column 4 lines 1-10.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Fahlvik and Lewis et al. thereby satisfying the applicant's invention because the Fahlvik reference does not preclude from said organ to include the kidney and the Lewis et al. reference provides the same contrast agents as in Fahlvik to image the kidney. The Lewis et al. reference discloses similar contrast agent method as in Fahlvik but now applies it to include the assessment of the physiological and morphological state of the kidney as taught by the applicant.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Dean (US 4,612,185) discloses methods and compositions for enhancing magnetic resonance imaging.
2. Gunther et al. (US 6,123,920) discloses superparamagnetic contrast media coated with starch and polyalkylene oxides.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Runa S. Qaderi whose telephone number is (703) 605-4285. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RSQ

RSQ

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700